REMARKS

This is a full and timely Response to the outstanding final Office Action mailed December 8, 2003. Applicant submits that the present amendments do not raise any new issues and will not require additional searching by the Examiner. Moreover, Applicant respectfully requests that the Amendment be entered because the Amendment places the claims in condition for allowance or reduces issues for appeal.

Amendments to the Claims

Independent claims 1 and 19 are amended to replace the term "alter" or "altering" with --lower- or --lowering-- respectively. Basis for this amendment is found in the specification as originally filed, for example, on pages 31-32.

Claim 23 is amended to clarify that the claimed medical device interiorly shifts a pathology's maximum electrical resistance when in contact with the pathology. Basis for this amendment is found in the specification as originally filed, for example, in Figure 30 and on page 31.

Claims 25 and 26 are amended to delete the term "in lateral electrical potential".

Claim 30 is amended to clarify that the medical device induces an analgesic effect by interiorly shifting a pathology's maximum electrical resistance when applied to the pathology. Basis for this amendment is found in the specification as originally filed, for example, Figure 30.

Claim 32 is amended to incorporate the limitations of Claim 33.

Claim Objections

Claim 33 is objected to as being of improper dependent form. Applicant has cancelled claim 33. Therefore, the objection is moot.

Claim Rejections Under 35 U.S.C. § 112

Claims 24 and 33 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the application recards the invention. Applicant has cancelled claims 24 and 33. Therefore, the rejection is moot.

Rejection of Claims 1, 4, 13 and 14 Under 35 U.S.C. § 102

Claims 1, 4, 13 and 14 are rejected under 3.5 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,520,664 ("Bricault, Jr. et al."). The Office Action concludes that Bricault, Jr.

et al. discloses polymeric implants at column 4, line 64 and 65. These polymeric implants allegedly include antimicrobrial coatings such as gold, silver, platinum, etc. The Office Action further notes that silver and other antimicrobrial metals inherently possess the property of altering an electrodynamic process of a portion of the body in which they contact, specifically the portion of the body containing wound exits. Additionally, the Office Action notes that the device of Bricault, Jr. et al. is capable of producing a lateral shift in the electrical potential of a pathology. Finally the Office Action notes that Bricault, Jr. et al. allegedly discloses a tubular shaped catheter in Figures 5 and 6A which is allegedly capable of draining a wound or body cavity. Applicant respectfully traverses this rejection.

A proper rejection of a claim under 35 U.S.C § 102 requires that a single prior art reference disclose each element of the claim. *See e.g., W.L. Gore and Assoc., Inc. v. Garloc, Inc.* 721 F.2nd 1540, 220 USPQ 303,313 (Fed. Cir. 1983).

Claim 1 as amended is directed towards a medical device for treating a pathology in a portion of a living organism comprising at least one conductive layer wherein at least one conductive layer comprises a resistance of less than about 1,000 ohms per centimeter squared and a biologically inert polymer which is at least partially coated with a metal or a metal alloy and wherein the medical device is configured to passively lower the pathology's electrical potential when the at least one conductive layer is positioned to conductively bridge healthy surfaces surrounding the pathology.

Bricault, Jr. et al. does not anticipate claim 1 for at least the following reasons. First, Bricault, Jr. et al. does not disclose a medical device that passively lowers a pathology's electrical potential, for example from a first electrical potential to a more negative second electrical potential, when the medical device is positioned to conductively bridge healthy surfaces surrounding the pathology. Indeed, nothing in Bricault, Jr. et al. references electrical potentials in any manner or medical devices that affect electrical potentials of the pathology by forming conductive bridges between surrounding healthy tissues.

The Office Action appears to suggest that the device of Bricault, Jr. et al. inherently anticipates the claimed subject matter because the device of Bricault, Jr. et al. is allegedly capable of producing a lateral shift and electric potential of a pathology. Applicant respectfully disagrees.

The Office Action does not cite any reference or article to support the conclusion that the device of Bricault, Jr. et al. is capable of producing a lateral shift in electrical potential pathology. More importantly, Bricault, Jr. et al. does not disclose lowering a pathology's electrical potential. Accordingly, Bricault, Jr. et al. can not anticipate claim 1 either expressly or inherently.

Moreover, to establish inherency, the USPTO must provide extrinsic evidence which "'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, **and that it would be so recognized by persons of ordinary skill**. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (emphasis added). Applicant respectfully submits that no evidence has been presented to demonstrate that Bricault, Jr. et al. discloses a medical device that can passively lower the electrical potential of a pathology. There is no evidence in the record that one of ordinary skill would recognize that the device of Bricault, Jr. et al. can passively lower the electrical potential of a pathology. Nor is there any evidence in the record that the deficiencies in the disclosure are necessarily present in the device of Bricault, Jr. et al. Accordingly, Applicant respectfully requests that the rejection be withdrawn.

Claims 4, 13 and 14 ultimately depend from claim 1, and therefore incorporate all of the limitations of claim 1. Because Bricault, Jr. et al. does not disclose each element of claim 1, Bricault, Jr. et al. can not anticipate dependent claims 4, 13 and 14. In light of the above, Applicant respectfully submits that the rejection has been overcome.

Rejection of Claims 1, 4, 19, 23, 25-31 Under 35 U.S.C. § 102(e)

Claims 1, 4, 19, 23, 25-31 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,004,667 ("Sakurada et al"). The Office Action concludes that Sakurada et al discloses a bandage or wound dressing having a fibrous substrate coating with silver or nickel which inherently has a resistance of 1,000 ohms per centimeter or less. The Office Action notes that the reference discloses that metallic ions may be distributed into the body without galvanic action. Moreover, the Office Action concludes that when metallic material is placed in contact with the wound fluid an electrochemical reaction takes places, and depending upon the amount of metallic material introduces into the wound, an antimicrobal or analgesic effect occurs. The Office Action alleges that this effect is produced through an

conclusion that the Office Action makes concerning the production of an analgesic effect through an alteration or shift in electrical potential. The Office Action provides no reference or citation to support the conclusion that metallic material introduced into a wound produces an alteration or shift in electrical potential which cause an antimicrobial or analgesic effect. Accordingly, Applicant respectfully submits that the rejection should be withdrawn.

Applicant notes that the Office Action cites Khanna, A. et al. as disclosing that silver is known to be an analgesic compound. Applicant points out that the publication date of this reference is December 1997 (See Exhibit 1). Applicant's earliest effective filing date is September 22, 1997. Accordingly, Khanna, A. et al. is not prior art against the claimed subject matter. Moreover, Applicant submits that Khanna, A. et al. discloses orally administering silver compounds to mice which is distinguishable from conductively bridging a pathology with the claimed medical device to produce an analgesic effect. Khanna, A et al. does not disclose, teach or suggest that conductive medical devices as presently claimed can induce an analgesic effect by lowering the electrical potential of a pathology.

Additionally, Applicant notes that the Office Action concludes "[w]hen the metallic material is placed in contact with wound fluid, an electrochemical reaction takes place, and depending on the amount of metallic material is [sic] introduced into the wound, an antimicrobial or analgesic effect occurs. Such effect is produced through an alteration/shift in the electrical potential of the wound fluid in and around the wound site" Applicant respectfully requests that the Examiner provide objective support for this conclusion in the form of a reference or similar publication. Without such support, Applicant submits any rejection based on this unsupported conclusion is improper and should be withdrawn.

Moreover, Applicant respectfully submits that the rejection is based on impermissible hindsight in view of Applicant's disclosure. There is no objective evidence in the record of any prior art that discloses, teaches, or suggests, a medical device as presently claimed that produces an analgesic effect by shifting electrical potential. The only disclosure of such information is Applicant's specification. Without any evidence other than Applicant's specification to support this conclusion, the rejection is improperly based on hindsight and should be withdrawn.

Notwithstanding the foregoing, and in an effort to expedite prosecution of the present application, Applicant has amended claims 1 and 19 to indicate that the medical device is configured to passively lower the pathology's electrical potential. Despite the assumptions

Notwithstanding the foregoing, and in an effort to expedite prosecution of the present application, Applicant has amended claims 1 and 19 to indicate that the medical device is configured to passively lower the pathology's electrical potential. Despite the assumptions recited in the Office Action, Sakurada et al. fails to disclose a medical device that passively lowers a pathology's electrical potential. Accordingly Sakurada et al. can not anticipate independent claims 1 and 19.

Because claim 4 is dependent on claim 1, it incorporates all of the elements of claim 1. Therefore, Sakurada et al. can not anticipate claim 4 for the same reasons it can not anticipate claim 1.

Claim 19 is a method claim reciting the step, among others, of lowering the electrical potential of the pathology by conductively bridging healthy body surfaces surrounding the pathology with the claimed medical device. As discussed above, Sakurada et al. does not disclose a medical device that lowers the electrical potential of the pathology by conductively bridging healthy body surfaces surrounding the pathology. As a result of this deficiency, Sakurada et al. cannot anticipate claim 19.

Claim 23 is amended to clarify that the medical device interiorly shifts a pathology's maximum electrical resistance, for example from a surface region to a subsurface region. Nothing in Bricault, Jr. et al. discloses shifting the maximum electrical resistance of a pathology towards the interior. Notwithstanding the allegation that Bricault, Jr. et al. discloses a device that alters an electrodynamic process, Bricault, Jr, et al. fails to disclose a device that causes maximum electrical resistance of a pathology to move interiorly. Accordingly, Applicant submits the rejection is overcome.

Claims 25-30 all depend from claim 23, and therefore incorporate the limitations of claim 23. As discussed above, Bricault, Jr. et al. fails to disclose each element of claim 23. As result, Bricault, Jr. et al. cannot anticipate any claim dependent on claim 23.

Claim 32 is also amended to recite that the medical device interiorly shifts a pathology's lateral electrical potential. Bricault, Jr. et al. does not disclose a medical device that can shift a pathology's lateral electrical potential. Even if as the Office Action alleges Bricault, Jr. et al. discloses a device that alters an electrodynamic process of a body, Bricault, Jr. et al. does not disclose a medical device that can shift a pathology's lateral electrical potential. Therefore,

Bricault, Jr. et al. cannot anticipate claim 32.

Rejection of Claim 6 Under 35 U.S.C. § 102(b)

Claim 6 is rejected as anticipated by U.S. Patent No. 4,615,705 to Scales et al. Applicant respectfully traverses this rejection because Scales et al. fails to disclose the claimed subject matter. Claim 6 depends from claim 1 and incorporates the limitations of claim 1 including for example passively lowering a pathology's electrical potential when the at least one conductive layer is positioned to conductively bridge healthy surfaces surrounding the pathology. Scales et al. fails to teach at least this element, and therefore cannot anticipate claim 6.

Rejection of Claim 7 under 35 U.S.C. § 103

Claim 7 is rejected as obvious over Scales et al. because it allegedly would have been obvious to one of ordinary skill in the art to coat any implant with an antimicrobial coating to prevent microbial growth on the implant. Applicant respectfully traverses this rejection because Scales et al. fails to teach or suggest each element of the claim.

Relevant Law

The United States Patent and Trademark Office (USPTO) has the burden of showing a prima facie case of obviousness. In re Bell, 991 F.2d 781, 783 (Fed. Cir. 1993). In determining obviousness, the invention must be considered as a whole, and the claims must be considered in their entirety. Medtronic, Inc. v. Cardiac Pacemakers, Inc., 721 F.2d 1563, 1567 (Fed. Cir. 1983). A prima facie case of obviousness is established when the teachings from the prior art itself would have suggested the claimed subject matter to a person of ordinary skill in the art. In re Rhinehart, 531 F.2d 1048, 1051 (CCPA 1976). More specifically, the requirements for establishing a prima facie case of obviousness include: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations.

When a rejection depends on a combination of prior art references, the USPTO must show that there is some teaching, suggestion, or motivation to combine the references. In re Geiger, 815 F.2d 686, 688 (Fed. Cir. 1987). The mere fact that the prior art could be modified would not have made the modification obvious unless the prior art suggested the desirability of

the modification. In re Gordon, 733 F.2d 900, 902 (Fed. Cir. 1984). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991). Finally, obviousness may not be established using hindsight. W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1551 (Fed. Cir. 1983).

Analysis

Claim 7 depends from claim 1 and incorporates all the limitations of claim 1. As noted above with respect to claim 1, Scales et al. fails to teach or suggest a medical device configured to passively lower the pathology's electrical potential when the at least one conductive layer is positioned to conductively bridge healthy surfaces surrounding the pathology. Scales et al. cannot render claim 7 obvious for at least the reason that it fails to teach or suggest this limitation. Accordingly, the USPTO has failed to establish a prima facie case of obviousness, and the rejection is overcome.

Rejection of Claims 3, 5 and 8-12 under 35 U.S.C. § 103

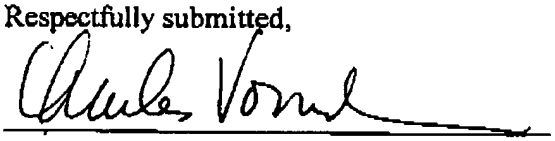
Claims 3, 5 and 8-12 are rejected as obvious over Sakurada et al. Applicant respectfully traverses this rejection for at least the reason that Sakurada et al. fails to teach or suggest each element of the claims.

Claims 3, 5, and 8-12 all depend from claim 1 and incorporate the limitations of claim 1. As discussed above, Sakurada et al. fails to teach or suggest a medical device configured to passively lower the pathology's electrical potential when the at least one conductive layer is positioned to conductively bridge healthy surfaces surrounding the pathology. Accordingly, the USPTO has failed to establish a prima facie case of obviousness, and the rejection is overcome.

CONCLUSION

In light of the foregoing amendments and for at least the reasons set forth above, Applicant respectfully submits that all rejections have been traversed, rendered moot, and/or accommodated, and that the now pending claims 1, 3-19, 23, and 25-32 are in condition for allowance. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested. If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned agent at (770) 933-9500.

Respectfully submitted,



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